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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,459	08/26/2003	Thomas Yung-Hui Chien	29985/01-530	5094

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MILLER, MATTHIS & HULL  
ONE NORTH FRANKLIN STREET  
SUITE 2350  
CHICAGO, IL 60606

EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/648,459

Applicant(s)

CHIEN ET AL.

Examiner

Sarah K. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 12-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 12-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1,4,8-10,12-15,18,19,21,23,27, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,292,321 to Lee in view of US Patent No. 5,976,153 to Fischell et al.

Lee discloses a stent delivery balloon catheter (14) that includes a distal tip with a diameter equal to the compressed diameter of the stent. The heating element (35) is a braided wire and is connected to electrical wires (31 and 34) (column 8, lines 39-58). The device includes a temperature-monitoring element (36) (column 8, lines 59-66). Lee discloses a method of using the device to deliver the stent that meets the claim limitations, including the step of monitoring temperature (column 11, lines 1-10). Lee fails to form the inner and outer tubes separately.

Fischell discloses another stent delivery balloon catheter with a distal tip (24) having a maximum outer diameter equal to or greater than the compressed diameter of the stent (40), as best shown in Figure 3. Fischell teaches that this type of catheter can have separate inner and outer tubes (11 and 12). Both the structures of Lee and Fischell define an inflation lumen for delivering fluid to the balloon. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Lee device to have separate inner and outer tubes, as taught by Fischell, as this is simply a substitution of functionally equivalent catheters that supply inflation fluid to a balloon of a stent delivery catheter. Further, it has been held that

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constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177,179.

Regarding claim 10, Fischell also includes radiopaque markers (13P and 13D) at the proximal and distal ends of the balloon (column 4, lines 28-30).

2. Claims 3 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Fischell, as applied above, and further in view of US Patent No. 5,035,694 to Kasprzyk et al.

The modified Lee device fails to include a heating element in the form of a coil, but forms the heating element has a braided wire sleeve (35) (column 8, lines 53-58). Kasprzyk discloses another balloon catheter with a heating element disposed on an inner tube within the balloon cavity. Kasprzyk teaches that the heating element can be a coiled wire (51), as shown in Figure 4. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the braided heating element of the modified Lee device as a coiled wire, as taught by Kasprzyk, as this is simply a substitution of functionally equivalent structures.

3. Claims 5-7,16,17,24-26,29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Fischell, and further in view of US Patent No. US Patent No. 6,579,305 to Lashinski.

Lee and Fischell fail to form the stent from a shape-memory metal, such as Nitinol. Lashinski discloses another heated balloon catheter. Lashinski teaches that this type of device is advantageous for delivering shape-memory stents because a sheath is not required and control is maintained over the position of the stent during

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expansion (column 2, line 34 through column 3, line 17). Lashinski teaches that a shape memory Nitinol stent can be crimped onto the balloon (column 4, line 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to deliver a shape-memory stent with the modified Lee device, as Lashinski teaches that the expansion and position of this type of stent may be highly controlled with a heated balloon catheter. The Nitinol stents may also have more desirable mechanical properties for a particular procedure than the polymeric stents disclosed by Lee.

Regarding the cooling step, Lee discloses the use of a cooling fluid injected into the balloon cavity to cool the stent (column 11, lines 20-65) and Lashinski discloses the use of a fluid to contract the stent onto the balloon (column 6, lines 26-35).

Considering these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject a cooling liquid into the balloon during insertion of the stent if it is necessary to prevent premature expansion of the stent due to body heat.

4. Claims 22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Fischell, and further in view of US Patent No. 6,174,327 to Mertens et al. Lee and Fischell simply do not state how the device is packaged, but Mertens teaches that a removable sheath can be disposed over the stent and removed before insertion (column 9, lines 12-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a removable sheath over the stent of Lee, as taught by Mertens, in order to protect the stent during shipping and storage.

***Response to Arguments***

5. Applicant's arguments with respect to claims 1,3-10, and 12-32 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SKW  
10/11/06

*Julian W. Woo*

**JULIAN W. WOO  
PRIMARY EXAMINER**